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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,573	02/20/2004	Geoffrey N. Holland	7135US05	7724

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EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3686	

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04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,573	HOLLAND ET AL.	
	Examiner	Art Unit	
	R. David RINES	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 9 January 2009. It is noted that this application benefits from Provisional Patent Application Serial Nos. 60/509,404 and 60/527,583 filed 10/7/08 and 12/5/08, respectively. Claims 1, 3, 4, and 12 have been amended. Claim 14 has been added. Claims 1-14 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[2] Claims 1 and 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al. (United States Patent #7,117,041) in view of Eggers et al. (United States Patent Application Publication #2006/0106649).

As per (currently amended) claim 1, Engleson et al. disclose a medication management system, for use with an information system and first and second input means; wherein the first input means delivers a medication order prescribed for a patient to the information system (Engleson et al.; col. 7, lines 36-42, col. 13, lines 3-21); and wherein the second input means inputs machine-readable patient-specific and drug container specific information from the patient and drug container (Engleson et al.; col. 8, lines 5-31, col. 13, lines 22-35); comprising: a medical device adapted to perform a medication order prescribed for a patient (Engleson et al.; col. 8, lines 5-31, col. 22-35); a medication management unit adapted for electronic communication with the information system, the medical device and the second input means (Engleson et al.; col. 14, lines 5-25 *see bedside CPU/medication administration module), the medication management unit having a processing unit and a storage medium coupled to the processing unit, the storage medium containing programming code executed by the processing unit to receive the delivery information from the second input means (Engleson et al.; col. 14, lines 5-25), request a medication order from the information system based on the delivery information from the second input means (Engleson et al.; col. 14, lines 5-25 *Examiner considers configuration/parameters to be a form of "an order"), receive the medication order from the information system (Engleson et al.; col. 14, lines 5-25), and send delivery programming code to the medical device based on the order (Engleson et al.; col. 14, lines 5-25); the medical device having a processor and a memory coupled to the processor, the memory containing programming code executed by the processor to receive and execute the delivery

programming code to perform a medication order prescribed for a patient (Engleson et al.; col. 14, lines 5-45).

Applicant has amended claim 1 with respect to the recited medical device to further specify. "…a medical device of a given type selected from among a plurality of types adapted to perform a medication order prescribed for a patient, the given type of medical device being identified by a device type identifier input as part of the medical device specific delivery information input by the second input means;"

As per this element, while Engleson et al. disclose multiple types of medical devices to be used by the system (Engleson et al.; col. 10, lines 45-60 *see infusion pumps and vital sign monitors), Engleson et al. fail to disclose identification of a device by type or type ID number.

However, as evidenced by Eggers et al. , the use of device ID specific to the device and configuration identifiers to define a specific device and configuration for a mediation delivery to a patient is well known in the art (Eggers et al.; paragraphs [0058] [0067]-[0070] *see serial number and configuration ID).

Applicant has further amended claim 1 with respect to the recited functions of the medication management unit to further include, "...receive the medication order from the information system, translate the medication order into delivery programming code executable by the given

type of medical device based on the device type identifier received from the second input means, and send the delivery programming code to the medical device based on the medication order;"

As per this element, while Engleson et al. disclose the device retrieving infusion parameters for the pump from the pharmacy (Engleson et al.; col. 13, lines 3-10 and col. 14, lines 5-20), Engleson et al. fail to explicitly teach translation of the prescription into delivery code or instructions.

However, Eggers et al. disclose "translate the medication order into delivery programming code executable by the given type of medical device based on the device type identifier received from the second input means, and send the delivery programming code to the medical device based on the medication order" (Eggers et al.; paragraphs [0068]-[0071] *see pharmacy system translates prescription into barcode indicating configuration ID, i.e., device type, and infusion parameters).

While Engleson et al. disclose maintaining tracking and records of use information with regard to clinical devices (Engleson et al.; col. 10, lines 45-61), Engleson et al. fail to disclose entering machine-readable device specific information from the device.

However, it is well-known in the art to enable networked medical devices to report device information to the overall system via the network, as evidenced by Eggers. Specifically,

Eggers et al. disclose a device that retrieves function specific configuration information based on the location of the device (Eggers et al; paragraphs [0031] [0066]-[0067]).

While Engleson et al. disclose delivery information including pump configuration parameters, Engleson et al. fails to describe modulations to the execution of the medication order.

However, it is well known in the art to enable adjustments to the medication order/delivery as a result of changes to the patient-specific input information (Eggers et al.; paragraphs [0048] [0057] [0061])

It would have been obvious to one or ordinary skill in the art at the time the invention was made to have combined the teachings of Engleson et al. with those of Eggers et al. The combined teachings would have provided a system-enabled method of integrating medical order information, infusion pump monitoring, and barcode technology to support real-time verification and charting of medications being administered to a patient to ensure that the right drug is given to the right patient (Engleson et al.; col. 7, lines 10-15). Additionally, one of ordinary skill would have reasonably employed known technologies to consider device specific information when determining proper configuration for the device (Eggers et al.; paragraphs [0067] [0068]). The motivation to combine the teachings would have been to facilitate efficient and accurate programming of a medical treatment device while ensuring that the prescribed treatment

conforms with institutional guidelines, laboratory results, or patient vital signs (Eggers et al.; paragraphs [0009] [0037] [0040]).

As per (currently amended) claim 3, Eggers et al. disclose a system wherein the medication management unit programming code orders the medical device to start execution of the delivery programming code and thereby performance of the medication order (Eggers et al.; paragraph [0048]).

As per (currently amended) claim 4, Eggers et al. disclose a system wherein the medication management unit programming code orders the medical device to stop execution of the delivery programming code and thereby performance of the medication order (Eggers et al.; paragraphs [0037]-[0040]).

NOTE: Regarding claim 4, while Eggers et al. disclose modification of the infusion parameters based on input patient data, Eggers et al. fail to specifically indicate that a stop order can be given. However, Examiner submits that if a modification of the parameters including altering infusion rate can be directed to the device, then reasonably and obviously, a stop order could be given as well.

As per claim 5, Eggers et al. disclose a system wherein the medication management unit programming code modulates a current medication order in the medical device (Eggers et al.;

paragraph [0040]).

As per claim 6, Eggers et al. disclose a system wherein the medication management unit programming code establishes a patient-specific rule set for the delivery programming code, and orders the medical device to modulate performance of the medication order by adjusting the patient-specific rule set (Eggers et al.; paragraphs [0037]-[0040]).

As per claim 7, Eggers et al. disclose a system wherein the medication management unit programming code orders the medical device to adjust the patient-specific rule set based on updated patient-specific information (Eggers et al.; paragraphs [0037]-[0040] [0059]).

As per claim 8, Eggers et al. disclose a system wherein the medication management unit is in electronic communication with a monitoring device to receive the updated patient-specific information (Eggers et al.; paragraphs [0037]-[0040] [0059]).

As per claim 9, Eggers et al. disclose a system wherein the medication management unit is in electronic communication with a lab and receives lab results including the updated patient-specific information (Eggers et al.; paragraphs [0037] [0039] Fig. 2).

As per claim 10, Eggers et al. disclose a system wherein the medication management unit

requires a caregiver to confirm the modulation (Eggers et al.; paragraph [0070] *Eggers requires user validation on all settings).

As per claim 11, Eggers et al. disclose a system wherein the confirmation by the caregiver takes place at the medical device (Eggers et al.; paragraph [0070]).

As per (currently amended) claim 12, Engleson et al. disclose a method for delivering programming code from an information system to perform a medication order prescribed for a patient to a medical device, comprising: delivering a medication order prescribed for a patient to an information system via a first input means (Engleson et al.; col. 7, lines 36-42, col. 13, lines 3-21 *see medication order entered via network); inputting machine-readable patient-specific and drug container specific information from the patient and drug container respectively, to a second input means (Engleson et al.; col. 8, lines 5-31, col. 13, lines 22-35 *see barcode entry); receiving the delivery information from the second input means at a medication management unit (Engleson et al.; col. 13, lines 49-67, col. 14, lines 5-25 *see parameters/configuration information); requesting an order from an information system based on the delivery information from the second input means at the medication management unit (Engleson et al.; col. 14, lines 5-25 NOTE: Examiner considers the parameters/configuration data to be a form of "an order"); receiving an order from the information system at the medication management unit (Engleson et al.; col. 14, lines 5-25); sending a delivery programming code to the medical device

based on the order at the medication management unit (Engleson et al.; col. 14, lines 5-25); receiving the delivery programming code at the medical device to perform a medication order prescribed for a patient (Engleson et al.; col. 14, lines 5-25);

While Engleson et al. disclose maintaining tracking and records of use information with regard to clinical devices (Engleson et al.; col. 10, lines 45-61), Engleson et al. fail to disclose entering machine-readable device specific information from the device.

However, it is well-known in the art to enable networked medical devices to report device information to the overall system via the network, as evidenced by Eggers. Specifically, Eggers et al. disclose a device that retrieves function specific configuration information based on the location of the device (Eggers et al; paragraphs [0031] [0066]-[0067]).

While Engleson et al. disclose delivery information including pump configuration parameters, Engleson et al. fails to describe modulations to the execution of the medication order.

However, it is well known in the art to enable adjustments to the medication order/delivery as a result of changes to the patient-specific input information (Eggers et al.; paragraphs [0048] [0057] [0061]).

Claim 12 has been amended to mirror the amendments made to claim 1 above. Accordingly, claim 12 is rejected in view of the teachings applied to claim 1 above.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to have combined the teachings of Engleson et al. with those of Eggers et al. The combined teachings would have provided a system-enabled method of integrating medical order information, infusion pump monitoring, and barcode technology to support real-time verification and charting of medications being administered to a patient to ensure that the right drug is given to the right patient (Engleson et al.; col. 7, lines 10-15). Additionally, one of ordinary skill would have reasonably employed known technologies to consider device specific information when determining proper configuration for the device (Eggers et al.; paragraphs [0067] [0068]). The motivation to combine the teachings would have been to facilitate efficient and accurate programming of a medical treatment device while ensuring that the prescribed treatment conforms with institutional guidelines, laboratory results, or patient vital signs (Eggers et al.; paragraphs [0009] [0037] [0040]).

As per (newly added) claim 14, Engleson et al. disclose a machine readable device ID label (Engleson et al.; col. 8, lines 25-31, col. 10, lines 45-67 and col. 11, lines 1-15).

Regarding claim 14, the statements of obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claim 14 and are herein incorporated by reference.

[3] Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., in view of Eggers et al., and further in view of Examiner's Official Notice.

Regarding claims 2 and 13, Eggers et al. disclose a system and method wherein the machine readable delivery information includes caregiver specific information from the caregiver and the medication management computer determines caregivers authorized to administer drugs to the patient (Eggers et al.; paragraph [0061]).

While Eggers et al. requires that parameters are changed by persons with the necessary authorizations, Eggers et al. fail to recite generating a list and comparing the caregiver to the listed of authorized caregivers.

However, Examiner takes Official Notice that it is well known in the medical informatics art to store a list of individuals and use the list to determine if a caregiver is authorized to treat the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed well-known techniques to determine authorization status of individuals accessing a hospital information system to treat a patient with the motivation of ensuring that

only qualified employees have access to confidential patient data and are in a position to administer treatment to the patient.

Response to Remarks/Amendment

Applicant's remarks filed 9 January 2009 have been fully considered but they are not persuasive. Applicant's remarks are directed to the amended limitations of claims 1 and 12 and are deemed to have been addressed in the preceding sections of the instant Office Action.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 9 January 2009 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Engleson et al. and Eggers et al, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David RINES whose telephone number is (571) 272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JERRY O'CONNOR can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/R. D. R./
Examiner, Art Unit 3686
April 13, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686